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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,412	07/23/2004	Takashi Yasukochi	KUZ-0018	3951

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10/24/2007

EXAMINER
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CHEUNG, WILLIAM K

ART UNIT	PAPER NUMBER
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1796

MAIL DATE	DELIVERY MODE
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10/24/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/502,412	<b>Applicant(s)</b> YASUKOCHI ET AL.	
	<b>Examiner</b> William K. Cheung	<b>Art Unit</b> 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 September 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 5,7,10-12,16-19,21-23,27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5,7,10-12,16-19,21-23,27 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. The examiner acknowledges the receipt of the amendment after final filed September 19, 2007. In view of the applicants' argument filed, the amendment after final has been entered. Claims 1-4, 6, 8-9, 13-15, 20, 24-26 have been cancelled, and new claims 27, 28 have been added. Claims 5, 7, 10-12, 16-19, 21-23, 27, 28 are pending.

2. In view of the amendment filed September 19, 2007, the rejection of Claims 10-12, 21-23 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Matsumoto et al. (US 5,532,373), is withdrawn.

3. After a careful re-evaluation of the claims, in view of the following issues, the allowability of Claims 15, 26 is withdrawn.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1796

5. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 19 (line 3-4) recites the limitation "N-vinyl-2-pyrrolidone" is considered indefinite. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1796

8. Claims 5, 7, 10-12, 16-19, 21-23, 27, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamiyama (WO 99/02141) in view of Matsumoto et al. (US 5,532,373).

*The invention of claims 5, 7, 10-12, 16-19, 27 relates to a **process** for the production of a medical patch, said process comprising:*

*(a) **dissolving in a lower alcohol:***

*(i) **a hormonal drug** selected from **estradiol and norethisterone acetate**; and*

*(ii) **an acrylic polymer or a methacrylic polymer** having at least **one hydroxyl or carboxyl group** in a **crosslinkable monomer unit**;*

*(b) **adding** to the solution of step (a) one or more crosslinking agents selected from the group consisting of **metal alcoholates, boric acid, borate and borate ester**;*

*(c) **spreading** the mixture of step (b) on a film; and*

*(d) **thermally crosslinking the polymer** of (ii) with the one or more crosslinking agents of step (b) **either simultaneously with or followed by laminating to a support**.*

*The invention of claims 5, 7, 21-23, 28 relates a **process** for the production of a medical patch, said process comprising:*

*(a) **dissolving in a lower alcohol:***

*(i) **a drug** selected from **estradiol and norethisterone acetate**; and*

*(ii) **one or more crosslinking agents** selected from the group consisting of **metal alcoholates, boric acid, borate and borate ester**;*

Art Unit: 1796

*(b) adding to the solution of step (a) an acrylic polymer or a methacrylic polymer having at least one hydroxyl or carboxyl group in a crosslinkable monomer unit to the solution;*

*(c) spreading the mixture of step (b) on a film; and*

*(d) thermally crosslinking the polymer of step (b) with the one or more crosslinking agents of (ii) either simultaneously with or followed by laminating to a support.*

Kamiyama (abstract) discloses a process for preparing transdermal patches comprising an adhesive. Kamiyama (page 5, line 20-28) discloses that the preparation of the adhesive compositions mixing acrylic based materials and polar monomers such as hydroxyethyl acrylate (typically is referred as 2-hydroxyethylacrylate) and hydroxypropyl acrylate (typically is referred as 3-hydroxypropyl acrylate), and vinyl pyrrolidone to enhance drug solubility of drugs (page 6, line 1-6), such as oestradiol and norethisterone (page 13, line 3-4).

Regarding the claimed "spreading the mixture on a film", Kamiyama (page 14, example 1) clearly discloses preparing the adhesive composition comprising the drugs by mixing, and applied to a backing film, and the film is allowed to dry. The disclosed drying step also indicates that the prepared adhesive film product is substantially free of water. Further, the mixing step teachings of Kamiyama also encompass the addition of the ingredients in all possible orders or sequences, which include the adding sequence of claims 27 and 28.

Art Unit: 1796

The difference between the invention of claims 5, 7, 10-12, 16-19, 21-23, 27, 28 and Kamiyama is that Kamiyama employs peroxide as curing agent, while the claimed invention involves the use of boric acid.

Matsumoto et al. (col. 1, line 12-33) disclose a process for preparing a photopolymerizable composition for producing lithographic sheets or films, resin reliefs, resists or photomasks or printed circuit board manufacture, black and white or color transfer development sheets or development sheets. Matsumoto et al. (col. 29, 23-38) clearly disclose that the adhesive having a film backing is capable of releasing its content (a dye or a drug). Further, Matsumoto et al. (col. 27, line 65-67) disclose that the composition comprises polyols, a lower alcohol (col. 29, line 21; col. 38, line 10-13), and crosslinking agent such as boric acid (col. 36, line 4). In view of such disclosure, it would not be difficult to one of ordinary skill in art that the material compositions of Matsumoto et al. and Kamiyama are very similar, particularly relating to the use of adhesive film for release a substance. Therefore, when Matsumoto et al. (col. 40-43, examples 3-5) disclose a shorter time required for drying at about 100 °C for 2 minutes, and at about 50 °C for 15 minutes when boric acid is used, motivated by the expectation of success of reducing the drying or curing time of Kamiyama, it would have been obvious to one of ordinary skill in art to replace the peroxide curing system of Kamiyama with the boric acid curing system of Matsumoto et al. to obtain the invention of claims 5, 7, 10-12, 16-19, 21-23, 27, 28.

### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William K. Cheung whose telephone number is (571) 272-1097. The examiner can normally be reached on Monday-Friday 9:00AM to 2:00PM; 4:00PM to 8:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David WU can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



William K. Cheung, Ph. D.

Primary Examiner

**WILLIAM K. CHEUNG  
PRIMARY EXAMINER**

October 19, 2007